

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No.: 14-829 (SLR)
)	
ACTAVIS ELIZABETH LLC,)	
)	
Defendant.)	

**PLAINTIFFS' FIRST SET OF REQUESTS FOR DOCUMENTS AND
THINGS TO DEFENDANT (REQUEST NOS. 1-102)**

Plaintiffs Orexo AB and Orexo US, Inc. (collectively, "Orexo" or "Plaintiffs") hereby request that Defendant Actavis Elizabeth LLC ("Actavis" or "Defendant") serve written responses to these Requests and produce the following documents for inspection and copying within thirty days of service, at the Office of Milbank, Tweed, Hadley & McCloy LLP, 1 Chase Manhattan Plaza, New York, New York 10005-1413, in accordance with Rules 26 and 34 of the Federal Rules of Civil Procedure and the Instructions and Definitions included at the end of this set of Requests. Documents in the possession, custody or control of Actavis, Inc., including all affiliates and subsidiaries thereof, shall be provided in response to these requests, pursuant to the terms of the September 22, 2014 Stipulation and Order. (D.I. 12, 13). Documents in the possession, custody or control of any counsel to Actavis are deemed to be in the possession, custody or control of Actavis.

REQUESTS

REQUEST NO. 1

Actavis's ANDA.

Actavis maintains in its inventory and used, may use, or meets its specifications for use in making Actavis's ANDA Product.

REQUEST NO. 15

All batch records, specification sheets, certificates of analysis, testing, analyses, correspondence, reports and other documents and things concerning each substance produced at each stage of production during the manufacture of Actavis's ANDA Product.

REQUEST NO. 16

All correspondence, reports and other documents and things concerning each batch of Actavis's ANDA Product made pursuant to, listed in, or referenced in ANDA No. 20-6258.

REQUEST NO. 17

50 grams (10 samples, 5 grams each) of each raw material used to make Actavis's ANDA Product, packaged and shipped consistent with the way Actavis maintains these raw materials.

REQUEST NO. 18

50 grams (10 samples, 5 grams each) of each raw material actually used to make Actavis's ANDA Product (with copies of the lot numbers drawn from), packaged and shipped consistent with the way Actavis maintains these raw materials.

REQUEST NO. 19

50 grams (10 samples, 5 grams each) of the Intermediate Products following each manufacturing steps, including without limitation any sifting, granulation, dry screening, milling, blending, and drying steps, packaged and shipped consistent with the way Actavis maintains Intermediate Products.

REQUEST NO. 20

240 tablets of each dosage form of Actavis's ANDA Product and any package inserts or instructions to be included with the product when sold.

REQUEST NO. 21

Batch Records for each of the samples provided in response to Request Nos. 17-20.

REQUEST NO. 22

The DMF(s) for the active ingredients of Actavis's ANDA Product, including all correspondence with FDA relating to the DMF(s).

REQUEST NO. 23

All documents, agreements, and communications concerning the procurement and supply of the active ingredients of in Actavis's ANDA Product.

REQUEST NO. 24

All documents concerning Zubsolv[®].

REQUEST NO. 25

All documents and things concerning any bioequivalence of Actavis's ANDA Product and any Zubsolv[®] product formulation disclosed in the NDA for Zubsolv[®] (NDA No. 20-4242).

REQUEST NO. 26

All documents and things concerning any comparison between Zubsolv[®] and (i) any ANDA Product, including but not limited to Actavis's ANDA Product, or (ii) any prior art to the Patents-In-Suit or prior art to foreign equivalents to the Patents-In-Suit.

15. For all samples requested, Actavis must provide Plaintiff with shipping and storage details sufficiently in advance of shipping samples to permit Plaintiff to establish appropriate arrangements to maintain the samples' integrity and representative nature.

16. Samples that are produced in response to these requests should be produced to Orexo counsel in a manner consistent with the way Actavis or its supplier maintains these samples or in a manner that ensures the integrity of the items produced.

17. In addition, Actavis must contact Plaintiff sufficiently in advance of shipping samples to permit Plaintiff to provide a shipping address (or addresses) and assure that appropriate personnel are present to receive the requested samples.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Regina Murphy

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*Attorneys for Plaintiffs
Orexo AB and Orexo US, Inc.*

November 18, 2014

CERTIFICATE OF SERVICE

I hereby certify that I caused copies of the foregoing document to be served on

November 18, 2014, upon the following in the manner indicated:

John C. Phillips, Jr., Esquire
Megan C. Haney, Esquire
David A. Bilson, Esquire
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*VIA HAND DELIVERY AND
ELECTRONIC MAIL*

Michael K. Nutter, Esquire
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VIA ELECTRONIC MAIL

/s/ Regina Murphy

Regina Murphy (#5648)

EXHIBIT 2

REDACTED
IN ITS
ENTIRETY

EXHIBIT 3

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

OREXO AB and OREXO US, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 14-829 (SLR)(SRF)
)	
ACTAVIS ELIZABETH LLC,)	
)	
Defendant.)	

STIPULATION AND [PROPOSED] ORDER AMENDING SCHEDULE

This stipulation is made by and between Orexo AB and Orexo US, Inc. and Actavis Elizabeth LLC.

WHEREAS, the current schedule provides that fact discovery is to close on October 13, 2015;

WHEREAS, certain fact witnesses are unavailable for deposition prior to the close of fact discovery;

WHEREAS, the parties agree that extending the deadlines as described below would permit the completion of the depositions;

NOW THEREFORE, Plaintiffs and Defendant stipulate and agree, subject to the approval of the Court, as follows:

1. The Scheduling Order (D.I. 25, 10/31/14 oral order, as modified by D.I. 53) in this case, subject to the Court's availability and approval, is modified as follows:

Event	Existing Schedule	Proposal
Close of fact discovery	Oct. 13, 2015	Nov. 17, 2015
Final infringement and invalidity contentions; supplementation of identification of accused products and invalidity references	Oct. 15, 2015	Nov. 20, 2015
Status conference to discuss “scope of case” and expert discovery	Oct. 20, 2015, 3:30 p.m.	At court’s convenience, after Nov. 20, 2015
Opening expert reports	Nov. 13, 2015	Dec. 14, 2015
Rebuttal expert reports	Dec. 18, 2015	Jan. 22, 2016
Supp. expert reports (e.g., re secondary considerations)	Jan. 15, 2016	Feb. 19, 2016
Close of expert discovery	Feb. 29, 2016	Mar. 16, 2016
Exchange fact witness lists (must have been disclosed during fact discovery)	Mar. 29, 2016 (“within one month following the close of expert discovery”)	Apr. 11, 2016 (within 2 weeks following close of expert discovery)
Status conference re expert discovery (e.g., plans for Daubert motions)	March 23, 2016, 3 p.m.	
Exchange rebuttal fact witness lists (must have been disclosed during fact discovery)	Apr. 29, 2016 (“within one month of receipt of [opening] fact witness list”)	
Pretrial conference	May 11, 2016, 4:30 p.m.	
Trial	7-day bench trial beginning June 6, 2016	
Expiration of 30-month stay	Nov. 16, 2016	

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IT IS SO ORDERED this _____ day of _____, 2015

The Hon. Sue L. Robinson
United States District Judge

EXHIBIT 4

**THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

OREXO AB and OREXO US, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 14-829 (SLR)(SRF)
)	
ACTAVIS ELIZABETH LLC,)	
)	
Defendant.)	

**DEFENDANT’S RESPONSES AND OBJECTIONS TO PLAINTIFFS’ FIRST SET OF
REQUESTS FOR DOCUMENTS AND THINGS (REQUEST NOS. 1-102)**

Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Defendant Actavis Elizabeth LLC (“Actavis”) hereby submits its Objections and Responses to Plaintiffs’ First Set of Requests for Documents and Things (“the Requests”) based on information and documents presently available as a result of a search and review process that is continuing. Actavis reserves the right to supplement and/or amend these responses as necessary.

GENERAL OBJECTIONS

Each of these objections is applicable to each of the Requests and is incorporated into each and every one of Actavis’ responses as though fully set forth therein, and is in addition to any specific objection stated for a particular Request.

1. Actavis objects to the Requests to the extent they purport to require Actavis to provide information on a schedule that conflicts with the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware; the Default Standard for Discovery, Including Discovery of Electronically Stored Information (“the Default Standard”); the Patent Case Order for Scheduling (D.I. 15); or the Court’s Scheduling Order. Subject to the objections identified herein, Actavis will produce responsive documents according to the timeline

REQUEST NO. 16

All correspondence, reports and other documents and things concerning each batch of Actavis's ANDA Product made pursuant to, listed in, or referenced in ANDA No. 20-6258.

RESPONSE:

In addition to its General Objections, Actavis objects to this Request on the grounds that it is unduly burdensome, overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Not "all correspondence, reports and other documents and things concerning each batch" are relevant to the issues in this case. In addition, Actavis objects to the extent that this Request seeks information, documents, and/or things protected by the attorney-client privilege, the attorney work-product doctrine, and/or other applicable privileges. Actavis will not produce documents that are protected from disclosure by an applicable privilege. Actavis further objects to this Request to the extent it seeks information regarding products other than Actavis' ANDA Product or Zubsolv®. Actavis will not produce documents related to products other than its ANDA Product or Zubsolv®.

Subject to these objections, Actavis will, consistent with the schedule imposed by the Court's scheduling order, produce relevant, responsive, and non-privileged documents that are in its possession, custody, or control and that can be located after a reasonably diligent search regarding Actavis' ANDA, amendments thereto, and correspondence with the FDA regarding Actavis' ANDA.

REQUEST NO. 17

50 grams (10 samples, 5 grams each) of each raw material used to make Actavis's ANDA Product, packaged and shipped consistent with the way Actavis maintains these raw materials.

RESPONSE:

In addition to its General Objections, Actavis further objects to this Request as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Actavis has already disclosed to Plaintiffs through the production of its ANDA the identity and characteristics of its ANDA Product. Physical samples of the raw materials used in the ANDA Product are not relevant to any issue in this case. Actavis further objects to this Request to the extent that it calls for the production of a controlled substance.

Subject to and without waiver of its objections, Actavis will produce 50 tablets of each dosage strength of its ANDA Product.

REQUEST NO. 18

50 grams (10 samples, 5 grams each) of each raw material actually used to make Actavis's ANDA Product (with copies of the lot numbers drawn from), packaged and shipped consistent with the way Actavis maintains these raw materials.

RESPONSE:

In addition to its General Objections, Actavis further objects to this Request as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Actavis has already disclosed to Plaintiffs through the production of its ANDA the identity and characteristics of its ANDA Product. Physical samples of the raw materials used in the ANDA Product are not relevant to any issue in this case. Actavis further objects to this Request to the extent that it calls for the production of a controlled substance.

Subject to and without waiver of its objections, Actavis will produce 50 tablets of each dosage strength of its ANDA Product.

REQUEST NO. 19

50 grams (10 samples, 5 grams each) of the Intermediate Products following each manufacturing steps, including without limitation any sifting, granulation, dry screening, milling, blending, and drying steps, packaged and shipped consistent with the way Actavis

maintains Intermediate Products.

RESPONSE:

In addition to its General Objections, Actavis further objects to this Request as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Actavis has already disclosed to Plaintiffs through the production of its ANDA the identity and characteristics of its ANDA Product. Physical samples of the “Intermediate Products” are not relevant to any issue in this case. Actavis further objects to this Request to the extent that it calls for the production of a controlled substance.

Subject to and without waiver of its objections, Actavis will produce 50 tablets of each dosage strength of its ANDA Product.

REQUEST NO. 20

240 tablets of each dosage form of Actavis’s ANDA Product and any package inserts or instructions to be included with the product when sold.

RESPONSE:

In addition to its General Objections, Actavis further objects to this Request as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Actavis has already disclosed to Plaintiffs through the production of its ANDA the identity and characteristics of its ANDA Product. Physical samples of the ANDA Product are not relevant to any issue in this case. Actavis further objects to this Request to the extent that it calls for the production of a controlled substance.

Subject to and without waiver of its objections, Actavis will produce 50 tablets of each dosage strength of its ANDA Product.

PHILLIPS GOLDMAN & SPENCE, P.A.

Dated: December 18, 2014

/s/ John C. Phillips, Jr.

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EXHIBIT 5



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April 29, 2015

VIA ELECTRONIC MAIL

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Re: *Orexo AB and Orexo US, Inc. v. Actavis Elizabeth LLC* (Zubsolv®), Case No. 14-829

Dear Anna:

We write in response to your April 14 letter alleging certain deficiencies in Actavis' responses to various Orexo discovery requests. As a preliminary matter, the vast majority of the issues you point to in your letter are premature or inapplicable in light of the parties' recent agreement to dismiss two patents-in-suit, add another patent to the case, and modify the scheduling order. In view of the parties' agreement, we are puzzled by your recent insistence that Actavis immediately respond to requests served before these fundamental changes to the litigation took place—changes brought about *at Orexo's request*. Nevertheless, we provide the responses below.

Document Requests

- 1. Documents relating to Actavis' ANDA Product, including research and development, manufacturing process, batch records, package inserts, communications and correspondence, pharmacokinetic and pharmacodynamics profiles, and the active ingredient and raw materials used to make Actavis' ANDA Product.**

You assert that "Orexo has not received all documents and things relating to research and development of Actavis' ANDA Product[.]" You point to a litany of document requests about which you allege "Actavis has not produced all documents[.]" Many of your objections are premature. The deadline for the completion of document production is June 19, with "substantial completion" by May 22 (under the timeline as amended by the parties' recent agreement). Subject to the objections set forth in its responses to Orexo's document requests, Actavis will produce responsive, non-privileged documents within the timeframe set forth in the Court's scheduling order (as amended). As you are no doubt aware, Actavis has been engaging in a rolling document production and will continue to do so.

Moreover, many of the documents you seek, to the extent they exist, would have been included in the ANDA Actavis has already produced, and to the extent you identify specific issues that you would like to discuss, we ask that you call those to our attention. It is unhelpful and insufficient to



April 29, 2015
Page 2

simply point to over 30 document requests and make a bare assertion that Actavis' document production (which is not yet complete) is somehow insufficient.

You specifically requested confirmation that Actavis will produce the Drug Master Files for the active ingredients used in its ANDA product. To the extent Orexo is seeking DMF(s) that are in the custody and control of any third party (e.g., for ingredients Actavis purchases from a third party), Orexo should request those documents from the relevant third parties.

You further requested that we "confirm that all persons involved or responsible for the research and development of Actavis's ANDA Product, or process used to make the buprenorphine and naloxone sublingual product used or contemplated for use in Actavis's ANDA Product have been identified and responsive documents have been provided to Orexo." We confirm that Actavis will produce responsive documents subject to its objections set forth in its responses to Orexo's document requests. With respect to the identification of "all persons" involved in the research and development of Actavis' ANDA product, we confirm that Actavis has identified the pertinent individuals. Furthermore, as noted in Actavis' interrogatory responses, pursuant to Federal Rule of Civil Procedure 33(d), the individuals involved in the development of its ANDA product can be ascertained from documents already produced and to be produced by Actavis.

You also pointed to Actavis' objection to Orexo's Request No. 10 regarding Certificates of Analysis and other testing documents. Actavis objected that those requests were "premature" as Orexo had not yet identified which claims of the patents-in-suit were asserted. That request remains premature in view of Actavis' recent assertion of the '330 patent and the fact that it has yet to serve infringement contentions. Nevertheless, Actavis confirms that it is not withholding responsive documents on the basis of this objection.

2. Samples of the Actavis' ANDA Product, raw materials, and intermediates.

Actavis will produce samples of its ANDA product. Specifically, Actavis will agree to produce 20 blister packs (totaling 200 tablets) of each of the two dosage strengths described in its ANDA. Please note that this product is a Schedule II controlled substance. In order to ship the samples, we will require Orexo's recipient to provide their DEA certification paperwork. The production of these samples must also be in accordance with the Protective Order. We will require a copy of an executed Protective Order undertaking from the individual(s) and entity who Orexo proposes will have access to the samples. The restrictions on the use and review of "Confidential" and "Highly Confidential" materials will also apply. Please provide this information so that Actavis can produce the samples.

Actavis does not have samples of intermediates and is therefore unable to produce them. Nor does Actavis routinely maintain samples of raw materials used in specific batches. Moreover, the raw materials used by Actavis are standard materials that Orexo can obtain from any number of suppliers in a manner that is more convenient, less burdensome, and less expensive than if Actavis were to order those samples on Orexo's behalf.

EXHIBIT 6



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June 19, 2015

VIA ELECTRONIC MAIL

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Re: *Orexo AB and Orexo US, Inc. v. Actavis Elizabeth LLC (Zubsolv®)*, Case No. 14-829

Dear Anna:

We write regarding several ongoing discovery issues in this litigation.

Document Production Schedule. To confirm what we discussed during our meet and confer conversation on June 5, 2015, Actavis has requested two additional weeks for the completion of its document production. As was explained to Judge Fallon at the June 8 conference, this request was made in order to accommodate the addition of the '330 patent to the litigation and the additional search terms the parties needed to run. As such, while Actavis intends to produce the vast majority of its documents today, it will complete its production by July 3, 2015. We are confused by Ms. Shum's comment in her June 8 e-mail indicating that Orexo has "concerns" about Actavis' request. We trust that the explanation subsequently provided at the hearing and reiterated above allays those concerns. If not, please let us know what they are.

Orexo's Deficient Discovery Responses. With respect to your first June 3 letter regarding the deficiencies Actavis previously identified in Orexo's discovery responses, we note several issues that remain unresolved.

First, Orexo still must update its responses to Interrogatories 4 and 7 regarding the alleged validity of the patents-in-suit and the identification of Orexo's asserted secondary considerations of nonobviousness, as we have been requesting since at least April. As we have explained both to Plaintiffs and to Judge Fallon, it is no answer for Orexo to demand that Actavis confirm that its "preliminary" invalidity contentions are "final." As you know, final contentions are not due until October 2, 2015. Pursuant to our discussion with Plaintiffs' counsel after the hearing, we can, however, and do confirm that the contentions and the combinations of prior art described in the text of the contentions are complete based on the discovery and investigation that has occurred to date. However, as you know, Actavis retains the right to amend those contentions as its investigation, the discovery process, and the claim construction proceedings continue. Please confirm by June 24 that in light of this confirmation, Orexo

WINSTON
& STRAWN
LLP

June 19, 2015
Page 6

Product samples. We are investigating whether any intermediates are available and will confirm in due course. As for the raw ingredients that Actavis purchases from suppliers, we will not produce samples. These are available to Orexo from the commercial suppliers identified in Actavis' ANDA (*see, e.g.,* ACT-ZUB-0262; -0331; -3007) and Orexo can purchase them just as easily as Actavis.

Documents related to the patents-in-suit. We confirm that Actavis is not withholding any non-privileged responsive documents. Actavis will produce non-privileged responsive documents located after a reasonable search.

Employment agreements. You have requested agreements between Actavis and any individuals involved with Actavis' ANDA Product. We do not agree that such documents are relevant to this case. Please explain in detail why you believe they are.

Historic document retention policies. Actavis has already produced its current document retention policy. As for historic policies, we do not understand the relevance of such documents (to the extent they even exist). We note that Orexo appears to agree with Actavis' position based on its response to Actavis' document request number 72. There is no allegation of spoliation in this matter. As such, Actavis will not produce historic document retention policies.

* * * *

Please confirm by June 24 the agreements noted above related to the production of profit, loss, and cost information and the proposed July 2 exchange of Orexo's identification of its alleged secondary considerations (in response to Actavis' Interrogatory Nos. 4 and 7), and Actavis' supplementation to Interrogatory No. 1 (related to noninfringement). We need to receive such confirmation so that we can consider whether the hearing before the Magistrate Judge will still be necessary. As to the remainder of the issues, please let us know a date when you are available to meet and confer. We look forward to hearing from you.

Sincerely,



Ivan M. Poullaos

cc: All Counsel (by e-mail)

EXHIBIT 7

REDACTED
IN ITS
ENTIRETY

EXHIBIT 8

REDACTED
IN ITS
ENTIRETY

EXHIBIT 9

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Drug Details

Drug Name(s)	ZUBSOLV
FDA Application No.	(NDA) 204242
Active Ingredient(s)	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE
Company	OREXO AB
Original Approval or Tentative Approval Date	July 3, 2013
Chemical Type	5 New formulation or new manufacturer
Review Classification	S Standard review drug

- [There are no Therapeutic Equivalents](#)
- [Label Information](#)
- [Approval History, Letters, Reviews, and Related Documents](#)
- [Medication Guide](#)¹⁰
- [REMS](#)¹¹

Products on Application (NDA) #204242

Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
ZUBSOLV	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE	EQ 1.4MG BASE; EQ 0.36MG BASE	TABLET;SUBLINGUAL	Prescription	No	None
ZUBSOLV	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE	EQ 5.7MG BASE; EQ 1.4MG BASE	TABLET;SUBLINGUAL	Prescription	Yes	None
ZUBSOLV	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE	EQ 8.6MG BASE; EQ 2.1MG BASE	TABLET;SUBLINGUAL	Prescription	No	None
ZUBSOLV	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE	EQ 11.4MG BASE; EQ 2.9MG BASE	TABLET;SUBLINGUAL	Prescription	No	None
ZUBSOLV	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE	EQ 2.9MG BASE; EQ 0.71MG BASE	TABLET;SUBLINGUAL	Prescription	No	None

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